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|-----------------------|------------|------------|----------------------------------|---------------------|------------------|--|
| APPLICATION NO.       | F          | ILING DATE | FIRST NAMED INVENTOR             | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
| 10/620,090            | 07/15/2003 |            | Josephus Wilhelmus A.M. van Oers | 294-165             | 7405             |  |
| 23869                 | 7590       | 04/06/2006 |                                  | EXAMINER            |                  |  |
| HOFFMAN<br>6900 JERIC |            | RON, LLP   |                                  | HORNING, MICHELLE S |                  |  |
| SYOSSET, NY 11791     |            |            |                                  | ART UNIT            | PAPER NUMBER     |  |
|                       |            |            |                                  | 1648                |                  |  |

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |  | Applicat        | ion No.                  | Applicant(s)           |        |  |  |  |  |  |
|--|--|-----------------|--------------------------|------------------------|--------|--|--|--|--|--|
| Office Action Summan   |  |                 | 90                       | VAN OERS ET AL.        |        |  |  |  |  |  |
|  | Office Action Summary  | Examine         | r                        | Art Unit               |        |  |  |  |  |  |
|  |  | Michelle        | -                        | 1648                   |        |  |  |  |  |  |
| Period fo  | The MAILING DATE of this communication or Reply  | n appears on th | e cover sheet with the c | orrespondence ad       | Idress |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                 |                          |                        |        |  |  |  |  |  |
| Status   |  |                 |                          |                        |        |  |  |  |  |  |
| 1) 又   | Responsive to communication(s) filed on 7/15/03.   |                 |                          |                        |        |  |  |  |  |  |
| · <u> </u>   |  | This action is  | non-final.               |                        |        |  |  |  |  |  |
| 3)□  | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits i  |                 |                          |                        |        |  |  |  |  |  |
|  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |                 |                          |                        |        |  |  |  |  |  |
| Disposition of Claims  |  |                 |                          |                        |        |  |  |  |  |  |
| 4)⊠  | Claim(s) 1-17 is/are pending in the applica  | ation.          |                          |                        |        |  |  |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |                 |                          |                        |        |  |  |  |  |  |
| 5)[  | Claim(s) is/are allowed.   |                 |                          |                        |        |  |  |  |  |  |
| 6)[  | Claim(s) is/are rejected.  |                 |                          |                        |        |  |  |  |  |  |
| 7)   | Claim(s) is/are objected to.   |                 |                          |                        |        |  |  |  |  |  |
| 8)🖂  | 8)⊠ Claim(s) <u>1-17</u> are subject to restriction and/or election requirement.   |                 |                          |                        |        |  |  |  |  |  |
| Applicati  | on Papers  |                 |                          |                        |        |  |  |  |  |  |
| 9)   | 9) The specification is objected to by the Examiner.   |                 |                          |                        |        |  |  |  |  |  |
|  | ☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |                 |                          |                        |        |  |  |  |  |  |
| •  | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |                 |                          |                        |        |  |  |  |  |  |
|  | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |                 |                          |                        |        |  |  |  |  |  |
| 11)  | 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |                 |                          |                        |        |  |  |  |  |  |
| Priority u   | ınder 35 U.S.C. § 119  |                 |                          |                        |        |  |  |  |  |  |
| _  | Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received. |                 |                          |                        |        |  |  |  |  |  |
| a)i  |  |                 |                          |                        |        |  |  |  |  |  |
|  |  |                 |                          | n Na                   |        |  |  |  |  |  |
|  | 2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage.   |                 |                          |                        |        |  |  |  |  |  |
|  | 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).                          |                 |                          |                        |        |  |  |  |  |  |
| * S  | * See the attached detailed Office action for a list of the certified copies not received.   |                 |                          |                        |        |  |  |  |  |  |
| and analysis a detailed action to a not of the dorumou depicts flot received.  |  |                 |                          |                        |        |  |  |  |  |  |
| Attachmen  | ((s)   |                 |                          |                        |        |  |  |  |  |  |
|  | e of References Cited (PTO-892)  |                 | 4) Interview Summary     | (PTO-413)              |        |  |  |  |  |  |
| 2) 🔲 Notic   | e of Draftsperson's Patent Drawing Review (PTO-948   |                 | Paper No(s)/Mail Da      | te                     |        |  |  |  |  |  |
|  | nation Disclosure Statement(s) (PTO-1449 or PTO/S<br>r No(s)/Mail Date   | B/08)           | 5) Notice of Informal Pa | atent Application (PTC | )-152) |  |  |  |  |  |

### **DETAILED ACTION**

# Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 13, drawn to antibodies specifically reactive to PrP<sup>Sc</sup> protein and hybridomas that produce them, classified in class 530, subclass 388.1 and in class 435, subclass 326.
- II. Claims 11-12, drawn to methods of prion detection, classified in class 435, subclass 5.
- III. Claims 14-17, drawn to methods of obtaining an antibody, classified in class 435, subclass 70.21.

The inventions are independent or distinct, each from the other because:

Inventions from Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product, as claimed, can be used in a materially different process, for example, as use as an affinity reagent in protein purification. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Application/Control Number: 10/620,090 Page 3

Art Unit: 1648

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, different products or monoclonal antibodies may be produced via methods using hybridomas or using recombinant DNA methods. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions II-III are unrelated because they are methods with different modes of operation, with respect to starting materials, physiological mechanisms, protocol procedures, and end products; therefore, each method is patentably distinct.

## Species Election

This application contains claims directed to the following patentably distinct species:

- 1. Species (A)-(D) of Claim 6, (A)-(E) of Claim 16 and (C)-(D) of Claim 17 represent the elected invention wherein the oligomerpeptide is derived from:
  - (A). human,
  - (B). ovine,
  - (C). murine,
  - (D). hamster and
  - (E). bovine.

The species are distinct because they differ in their physical and immunological properties as well as their activity in the life cycle of prion proteins; furthermore, they differ in their nucleic acid sequences and are distinct and unobvious in view of each other. Therefore, they are patently distinct.

The examination of species (A)-(E) in the method parameters would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 2 and 10 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Art Unit: 1648

# Notice of Possible Rejoinder

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Application/Control Number: 10/620,090 Page 6

Art Unit: 1648

### Joint Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michelle Horning, Ph.D.

Patent Examiner

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600